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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,511	12/14/2001	Arnold J. Reuser	24414-Y	3913

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NATH & ASSOCIATES
1030 15th STREET
6TH FLOOR
WASHINGTON, DC 20005

EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	7

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/014,511	Applicant(s) REUSER ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *30days* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16 and 18-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Claim 17 will not be considered as it is wholly unclear. As written, claim 17 could be read to encompass two distinct inventions, 1) a composition with capacity to be taken up my muscle cells and 2) milk of the non-human transgenic animal of claim 1. The claim could also encompass human acid.alpha-glucosidase with the milk from the transgenic animal of claim 1 added to it. The acid.alpha-glucosidase in the milk of the animal of claim 1 is not necessarily human acid.alpha-glucosidase.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 15-16, drawn to a transgenic non-human mammal expressing a transgene encoding acid.alpha-glucosidase into the milk of the mammal and use of the animal to produce acid.alpha-glucosidase by recovering the milk and the milk, classified in class 800;800, subclass 14;7.

II. Claim 11, drawn to a method of incorporating milk comprising acid.alpha-glucosidase into a food product, classified in class 424, subclass 439.

III. Claims 12-14, drawn to method of purifying acid.alpha-glucosidase from milk and the purified product, classified in class 530;530, subclass 412;350.

IV. Claims 18-53 and 62-67, drawn a pharmaceutical comprising acid.alpha-glucosidase and a method of treating disease using acid.alpha-glucosidase, classified in class 530;514;424, subclass 350;2;94.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the transgenic mammal can be used to produce a source of acid.alpha-glucosidase protein for purification while the methods of Invention II can be used to make a food product. The protocols and reagents required for the transgenic mammal and the methods of making a food product are materially distinct and separate. The mammal does not require the methods and the methods do not require the mammal. Furthermore, the inventions are classified differently and the burden required to search Inventions I and II together would be undue.

Inventions I and III are patentably distinct because the transgenic mammal can be used to produce a source of milk comprising acid.alpha-glucosidase while the methods of Invention III can be used to purify acid.alpha-glucosidase from milk. The protocols and reagents required for the transgenic mammal and the methods purifying are materially distinct and separate. The mammal does not require the methods and the methods do not require the mammal. Furthermore, the inventions are classified differently and the burden required to search Inventions I and III together would be undue.

Invention I and IV are patentably distinct because the transgenic mammal can be used to produce a source of milk comprising acid.alpha-glucosidase while the pharmaceutical and methods of Invention IV can be used to treat disease. The protocols and reagents required for the transgenic mammal and the pharmaceutical are materially distinct and separate. The mammal does not require the pharmaceutical and the methods do not require the mammal. Furthermore, the inventions are classified differently and the burden required to search Inventions I and IV together would be undue.

Inventions II and III are patentably distinct because the methods of Invention II can be used to generate a food product comprising acid.alpha-glucosidase while the methods of Invention III can be used to purify acid.alpha-glucosidase from milk. The protocols and reagents

required for the food product and the methods purifying are materially distinct and separate. The food product does not require the methods and the methods do not require the food product. Furthermore, the inventions are classified differently and the burden required to search Inventions II and III together would be undue.

Inventions II and IV are patentably distinct because methods of Invention II can be used to generate a food product comprising acid.alpha-glucosidase while the pharmaceutical of Invention IV can be used to treat disease intravenously. The protocols and reagents required for the methods and the pharmaceuticals are materially distinct and separate. The methods do not require the pharmaceutical and pharmaceuticals and do not require the methods of Invention II. Furthermore, the inventions are classified differently and the burden required to search Inventions II and IV together would be undue.

Inventions III and IV are patentably distinct because methods of Invention III can be used purify acid.alpha-glucosidase from milk while the pharmaceutical of Invention IV can be used to treat disease intravenously. The protocols and reagents required for the methods of purifying and the pharmaceutical are materially distinct and separate. The methods of purifying do not require the pharmaceuticals and the pharmaceuticals do not require the methods. Furthermore, the inventions are classified differently and the burden required to search Inventions III and IV together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner

Deborah Reynolds

DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600